

Drug Enforcement Administration, Justice

§ 1315.24

(i) The trend of (and recent changes in) the applicant's and the national rates of net disposal.

(ii) The applicant's production cycle and current inventory position.

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.

(iv) Yield and stability problems.

(v) Potential disruptions to production (including possible labor strikes).

(vi) Recent unforeseen emergencies such as floods and fires.

[72 FR 37448, July 10, 2007, as amended at 73 FR 73555, Dec. 3, 2008; 75 FR 10684, Mar. 9, 2010]

§ 1315.23 Procedure for fixing individual manufacturing quotas.

(a) In fixing individual manufacturing quotas for ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator shall allocate to each applicant who is currently manufacturing the chemical a quota equal to 100 percent of the estimated net disposal of that applicant for the next calendar year, adjusted—

(1) By the amount necessary to increase or reduce the estimated inventory of the applicant on December 31 of the current year to his estimated inventory allowance for the next calendar year, pursuant to § 1315.24, and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including:

(i) The trend of (and recent changes in) the applicant's and the national rates of net disposal,

(ii) The applicant's production cycle and current inventory position,

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes,

(iv) Yield and stability problems,

(v) Potential disruptions to production (including possible labor strikes), and

(vi) Recent unforeseen emergencies such as floods and fires.

(b) In fixing individual manufacturing quotas for a chemical, the Administrator shall allocate to each applicant who is not currently manufacturing the chemical a quota equal to 100 percent of the reasonably estimated net disposal of that applicant for the

next calendar year, as determined by the Administrator, adjusted—

(1) By the amount necessary to provide the applicant his estimated inventory allowance for the next calendar year, pursuant to § 1315.24; and

(2) By any other factors which the Administrator deems relevant to the fixing of the individual manufacturing quota of the applicant, including any of the following:

(i) The trend of (and recent changes in) the national rate of net disposal.

(ii) The applicant's production cycle and current inventory position.

(iii) The economic and physical availability of raw materials for use in manufacturing and for inventory purposes.

(iv) Yield and stability problems.

(v) Potential disruptions to production (including possible labor strikes).

(vi) Recent unforeseen emergencies such as floods and fires.

(c) On or before March 1 of each year the Administrator shall adjust the individual manufacturing quota allocated for that year to each applicant in paragraph (a) of this section by the amount necessary to increase or reduce the actual inventory of the applicant to December 31 of the preceding year to his estimated inventory allowance for the current calendar year, pursuant to § 1315.24.

§ 1315.24 Inventory allowance.

(a) For the purpose of determining individual manufacturing quotas pursuant to § 1315.23, each registered manufacturer shall be allowed as a part of the quota an amount sufficient to maintain an inventory equal to either of the following:

(1) For current manufacturers, 50 percent of his average estimated net disposal for the current calendar year and the last preceding calendar year; or

(2) For new manufacturers, 50 percent of his reasonably estimated net disposal for the next calendar year as determined by the Administrator.

(b) During each calendar year each registered manufacturer shall be allowed to maintain an inventory of a chemical not exceeding 65 percent of his estimated net disposal of that chemical for that year, as determined at the time his quota for that year was determined. At any time the inventory